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AWARD NUMBER: DAMD17-03-1-0109

TITLE: Telemedicine Based Ultrasound for Detecting Neonatal Heart Disease in  
Babies at Remote Military or Native American Health Care Facilities

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REPORT DATE: September 2009

TYPE OF REPORT: Final Addendum

PREPARED FOR: U.S. Army Medical Research and Materiel Command  
Fort Detrick, Maryland 21702-5012

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# REPORT DOCUMENTATION PAGE

Form Approved  
OMB No. 0704-0188

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1. REPORT DATE 1 September 2009			2. REPORT TYPE Final Addendum		3. DATES COVERED 15 Mar 2009 – 14 Aug 2009	
4. TITLE AND SUBTITLE  Telemedicine Based Ultrasound for Detecting Neonatal Heart Disease in Babies at Remote Military or Native American Health Care Facilities					5a. CONTRACT NUMBER	
					5b. GRANT NUMBER DAMD17-03-1-0109	
					5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S)  David J. Sahn, M.D., COL Robert Puntel, M.D., COL James Kinney, M.D.  E-Mail: sahnd@ohsu.edu					5d. PROJECT NUMBER	
					5e. TASK NUMBER	
					5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)  University of Oregon Portland, OR 97239					8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)  U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012					10. SPONSOR/MONITOR'S ACRONYM(S)	
					11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited						
13. SUPPLEMENTARY NOTES						
14. ABSTRACT  Our partnership of investigators from Madigan Army Medical Center at Fort Lewis, WA, and Oregon Health & Science University in Portland will test the hypothesis that trained primary care or nurse practitioners, with telemedicine supervision, perform cardiac ultrasound exams on neonates at risk for heart disease, and thereby impact time to diagnosis and outcomes. This study is targeted at MEDDACs within TriWest and Western Regional Medical Command. It will also include two Alaska Native Health Care Centers. Echocardiography has had major impact in the management of neonates suspected of having congenital heart disease. The expensive, specialized equipment and significant expertise to adequately perform and interpret these studies usually is present only in tertiary level medical centers with a pediatric cardiologist on staff. Initial results of a National Multicenter Neonatal Telemedicine Echo Outcomes Study, developed by the Principal Investigator, suggest that telemedicine-implemented diagnosis positively affects outcomes in infants suspected of having congenital heart disease. Our partnership has trained 37 non-cardiologists to perform neonatal echo and established a VTC over IP network on the DoD's high bandwidth MEDNET and NIPRNET. As of 2009, we have the capability to oversee neonatal echo exams from 4 military installations in the NW and in Alaska, as well as a large Alaska Native Health Center in Anchorage. We also upgraded the scanners used in our network to the latest architecture from Sonosite®: the fully digital phased array handheld ultrasound scanner, the MicroMaxx®. Modernization and standardization of VTC equipment is currently underway and will be completed by end of 2009.						
15. SUBJECT TERMS Echocardiography; Ultrasound; Telemedicine; Neonates; Congenital Heart Disease; Outcomes						
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT UU	18. NUMBER OF PAGES 32	19a. NAME OF RESPONSIBLE PERSON USAMRMC	
a. REPORT U	b. ABSTRACT U	c. THIS PAGE U			19b. TELEPHONE NUMBER (include area code)	

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## **INTRODUCTION:**

This impact and outcomes research proposal will specifically test the hypothesis that a method for reliable and rapid assessment of newborn infants at risk for heart disease can be developed for telediagnosis using a small hand-held ultrasound system with an appropriate high frequency transducer. The unique setting will be that the healthcare professional performing the examination may not be a cardiologist or a fully trained echocardiographer, but the examination will be monitored, supervised and guided using telemedicine links which will also allow control of the scanning system settings by the remote supervisor who is an expert Pediatric Cardiologist/echocardiographer. The program will assess diagnostic accuracy as the primary outcome variable and time to diagnosis, incidence of unnecessary transport and length of stay during initial hospitalization including transfer when it occurs, as secondary medical outcomes. Diagnosis will be established by testing at a referral center or examination and ultrasound performed by the expert consultant on a follow-up visit occurring at the referral site. In addition to any diagnostic findings of significance which are missed, we will survey and document adverse events in the patient's subsequent course, both medical and social (e.g.: parent/baby separation, parental anxiety). Each infant will be followed for 3 months from the time of the initial diagnosis encounter and will be compared to historical controls. Finally, our study will also include a financial outcomes/cost analysis.

### Summarized progress

As of 8/14/2009: A total of 102 consented subjects to date, no SAE/AE to report. Including 63 subjects enrolled at Madigan Army Medical Center and 1 subject at Alaskan Native Medical Center for training purposes. Consented TeleEcho performed to date includes 21 subjects at Bassett Army Community Hospital, 13 subjects at Naval Hospital Oak Harbor, 3 subjects at Naval Hospital Bremerton, and 1 subject at Weed Army Community Hospital. Col James B. Kinney, MD conducted two outpatient cardiac clinics at Bassett Army Community Hospital in 2009. Three 3-month follow-ups were accomplished during the clinics. Cardiac abnormalities such as ASD, PFO, PPS, VSD, coarctation and Tetralogy were recognized by TeleEcho and confirmed 100% with follow-up conventional echocardiography. The patients diagnosed with coarctation and Tetralogy underwent heart surgery and now doing well.

TeleEcho Project was selected and received AAMTI FY09 funding from Telemedicine & Advanced Technology Research Center (TATRC). The additional funds are being used to extend the life of the TeleEcho Project in order to demonstrate the effectiveness of the TeleEcho System Virtual User Interface, software which allows the reading pediatric cardiologist to control the sending site's ultrasound panel.

Currently Madigan, Bassett, Weed, American Native, Oak Harbor, Bremerton, and Bayne-Jones have received IRB approval and continuing approval for 2009. Blanchfield and Elmendorf will resubmit once new Principal Investigators complete all IRB requirements. HRPO has reviewed and approved Madigan, Bassett, Weed, American Native, Oak Harbor, Bremerton, Elmendorf and Bayne-Jones for enrollment. Yukon-Kuskokwim Health Corporation in Bethel, AK is expressing great interest in having the TeleEcho System installed and available for use; however, additional funding will need to be procured to add new systems at this point.

One TeleEcho Refresher Training Session was conducted with Alaskan Native Medical Center on 4 March 2009 using the TeleEcho System. All active sites have at least one trained provider and all the equipment necessary. Madigan, Bassett, Weed, Alaskan Native, and Oak Harbor and Bremerton received approvals to connect to local area networks and have converted to the MEDNET. All sites, except Yukon, have received the necessary medical equipment for the study and equipment swap out per CRDA has been completed. Modernization of VTC equipment is now underway with the assistance of AAMTI FY09 funding.

**BODY:****1- A full update on the status of all Human Subjects protocols and our qualifications to run interact with each base.**Summary of Human Subject Protocol:

- 8 sites with full IRB approval: Madigan, Bassett, Weed, Alaska Native, Bremerton, Oak Harbor, Elmendorf, and Bayne-Jones
- 1 sites for resubmission: Blanchfield
- 1 site on hold: Yukon

Madigan Army Medical Center (MAMC), Ft. Lewis, WA

- Institutional Review Board (IRB) Annual Continuing Review of protocol. The MAMC IRB approved continuation of the protocol on 5 March 2009, for the following sites: Bassett Army Community Hospital, Weed Army Community Hospital, and MAMC. Approval expires 17 February 2010.
- U.S. Army Medical Research and Material Command (USAMRMC), Human Subjects Research Review Board approved the subject protocol on 6 February 2004. Human Research Protections Office (HRPO) continuing review acceptance on 29 April 2009.
- No changes to staff in 2009.
- CITI - The Protection in Human Research Subjects Training is current for all investigators and staff.
- Curriculum Vitae are current for all investigators and staff.
- Drs Sahn, Puntel, & Kinney privileges are current.
- A total of 63 subjects enrolled at MAMC as training models during the TeleEcho Training Seminars.
- A total of 21 subjects have been enrolled from Bassett Army Community Hospital, of which 2 were enrolled in 2009.
- A total of 13 subjects were enrolled from Naval Hospital Oak Harbor, of which 12 were in 2009.
- A total of 3 subjects were enrolled from Naval Hospital Bremerton, all in 2009.
- 1 subject was enrolled at Weed Army Community Hospital in 2009.
- 1 subject was enrolled as a training model volunteer at Alaska Native Medical Center in 2009.
- Madigan's TeleEcho System is certified and registered on the USAMITC Bridge and fully operational on the MEDNET. The transition took longer than anticipated causing 3 months lapse in data collection in 2008.
- USAMITC forgot to notify anyone in the TeleEcho Project regarding a planned network upgrade. Any TeleEcho Polycom model 512 or FX on the MEDNET became incompatible due to the Codian that replaced the RADVision. 1-3 months of service interruption, site dependent, was caused due to this oversight in 2009. The service interruption could have been longer; however, Madigan Ophthalmology had a Tandberg 3000MXP not in use and agreed to loan it to the TeleEcho Project until a replacement was purchased or until they needed the equipment.
- COL Robert Puntel, principal investigator at Madigan received AAMTI FY09 funding. Funding is being used to continue the project. The Virtual User Interface will be installed and tested during TeleEcho calls. Funding paid for a Project Coordinator, VTC equipment modernization.

Bassett Army Community Hospital (BACH), Ft Wainwright, AK

- Annual Continuing Review of protocol. Approved during 5 March 2009 MAMC IRB meeting. Approval expires 17 February 2010. A separate protocol is unnecessary as BACH is under MAMC command and covered by MAMC IRB. BACH has our most currently approved consent form available for use.
- U.S. Army Medical Research and Material Command (USAMRMC), Human Subjects Research Review Board approved the subject protocol on 6 February 2004. HRPO continuing review acceptance on 29 April 2009.
- Changes to staff in 2009. Dr Steven Jay was removed from medical monitor when he moved to Ft Carson. MAJ Michael Thwing, MD took over medical monitor duties as of 8 April 2009. CPT Rebeckah Burns, MD was moved from Principal Investigator to Associate Investigator while on deployment to Iraq. CPT Peter Vickerman, MD was moved from Associate Investigator back to Principal Investigator once he returned from Iraq deployment. A MOR with staff updates was submitted to Chair, MAMC IRB on 22 June 2009.
- CPT Peter Vickerman, MD received initial TeleEcho Training on January 14-15, 2008. CPT Rebeckah Burns, MD received initial TeleEcho Training on May 6-7, 2008.
- CPT Peter Vickerman, MD was deployed to Iraq May 2008 - April 2009.
- CPT Rebeckah Burns, MD deployed for Iraq April 2009 with an anticipated return date of May 2010.
- CITI - The Protection in Human Research Subjects Training is current for all site investigators and medical monitor.
- Curriculum Vitae are current for all site investigators.
- Drs Sahn, Puntel, & Kinney privileges are current.
- Bassett's TeleEcho System is certified and registered on the USAMITC Bridge and was fully operational on the MEDNET until the USAMITC network upgrade at Bassett January 2009 that made the Polycom 512 obsolete. As a work around, IMD brings a borrowed VTC to the mother-baby-unit when needed for a TeleEcho.
- A total of 21 subjects have been enrolled at BACH, of which 2 were enrolled in 2009. We believe enrollment was low in 2008-2009 due to (1) Staff shortage from deployment schedules and physicians leaving; (2) Lack of a dedicated TeleEcho VTC system available for investigator to use in 2009; (3) Periods of network outage while transferring communications to MEDNET in 2008; and (4) Service interruption at Madigan caused by USAMITC's network upgrade in 2009. No SAE/AE to report.
- Three month follow-up conventional echocardiography was performed on 3 consented subjects by COL James, B. Kinney, MD during outpatient cardiac clinics held at Bassett.

Weed Army Community Hospital (WACH), Ft. Irwin, CA

- Annual Continuing Review of protocol. Approved during 5 March 2009 MAMC IRB meeting. Approval expires 17 February 2010. A separate protocol is unnecessary as WACH is under MAMC command and covered by MAMC IRB. WACH has our most currently approved consent form available for use.
- U.S. Army Medical Research and Material Command (USAMRMC), Human Subjects Research Review Board approved the subject protocol on 6 February 2004. HRPO continuing review acceptance on 29 April 2009.

- Changes to staff in 2009. MAJ Thomas Byrne, MD had a permanent change of duty station and was removed as medical monitor July 2009. CPT Peaches Richards, MD had a permanent change in duty station and was removed as Principal Investigator August 2009. CPT Ruth Faircloth, MD joined the study as the new Principal Investigator and CPT Ryan Larson, MD took over medical monitor duties. A MOR with staff updates was submitted to Chair, MAMC IRB on 15 July 2009.
- CPT Ruth Faircloth, MD received initial TeleEcho Training on December 18-19, 2007.
- Dr Ronald Williams and Margaret Williams, PNP, received TeleEcho Training at Madigan before transferring to WACH. Once they complete CITI training, they will be officially added to the study in 2009.
- CITI - The Protection in Human Research Subjects Training is current for all site investigators.
- Curriculum Vitae are current for all site investigators.
- Drs Sahn, Puntel, & Kinney privileges are current.
- Weed's TeleEcho System is certified and registered on the USAMITC Bridge and was fully operational until the USAMITC network upgrade in 2009 that made the Polycom 512 obsolete. As a work around, IMD installed a newer model Polycom until a permanent upgrade could be procured.
- Weed enrolled its first subject on 30 July 2009, CPT Ruth Faircloth's first day in clinic! The TeleEcho was actually conducted on 17 August 2009 after CPT Faircloth reassembled the system locally. We believe enrollment was low in 2008-2009 due to (1) Lack of commitment by the previous principal investigator; (2) Periods of network outage transferring communications to MEDNET in 2008; and (3) Service interruption at Madigan caused by USAMITC's network upgrade in 2009. No SAE/AE to report.

#### Naval Hospital Oak Harbor (NHOH), Oak Harbor, WA

- Annual Continuing Review of site-specific protocol. Naval Medical Center San Diego (NMCSD) IRB approved continuation of the protocol during 22 July 2009 meeting, for the following sites: Naval Hospital Oak Harbor and Naval Hospital Bremerton. Approval expires 22 July 2010.
- U.S. Army Medical Research and Material Command (USAMRMC), Human Subjects Research Review Board approved the subject protocol on 16 November 2007. Human Research Protections Office (HRPO) continuing review for 2009 is still waiting on Naval Medical Center San Diego to release the approval letter from 22 July 2009 IRB meeting.
- 3-Party Cooperative Research & Development Agreement (CRDA) between Naval Hospital Oak Harbor / Naval Hospital Bremerton and TRUE Research Foundation and Oregon Health & Science University expires 27 October 2009. Renewal is not anticipated since TRUE Research Foundation is no longer a participant in the project.
- Memorandum of Understanding (MOU) between Madigan Army Medical Center and Naval Hospital Oak Harbor (MCHJ-130-04) effective 27 October 2006 – 26 October 2009. The renewal has already been accepted by both parties with no change other than termination date. The new MOU should be in place before the other expires.
- DoD Assurance for Naval Hospital Oak Harbor, DoD N40027, expires 30 January 2010.
- No changes to staff in 2009 at Oak Harbor.
- LCDR Harlan Dorey received initial TeleEcho Training on December 9-10, 2008.

- CITI - The Protection in Human Research Subjects Training is current for all site investigators.
- Curriculum Vitae are current for all site investigators.
- Drs Sahn, Puntel, & Kinney privileges are current.
- Oak Harbor's TeleEcho System is certified and registered on the USAMITC Bridge to Madigan's outside gatekeeper. Since the Navy has not made the same network upgrades, the Polycom 512 is still operational; however, a bad Polycom power supply is preventing the codec from dialing out. In addition, the Navy will make the same network upgrade as USAMITC at which time the Polycom 512 will become obsolete. A new power supply will be purchased to prevent an interruption in service until the VTC system is modernized.
- A total of 13 subjects were enrolled from NHOH, of which 12 were in 2009. We believe enrollment was low in 2008-2009 due to (1) Delays by Naval Medical Center San Diego IRB; (2) Periods of network outage while transferring communications to MEDNET in 2008; (3) Service interruption at Madigan caused by USAMITC's network upgrade in 2009; and (4) Bad Polycom power supply. No SAE/AE to report.
- Due to the success of TeleEcho, the Principal Investigators at Madigan and Oak Harbor are establishing an outpatient cardiac clinic at Oak Harbor on a quarterly basis. Three month follow-up conventional echocardiography will be performed by COL Robert A. Puntel, MD during these outpatient cardiac clinics held at Oak Harbor.

Naval Hospital Bremerton (NHB), Bremerton, WA

- Annual Continuing Review of site-specific protocol. Naval Medical Center San Diego (NMCSD) IRB approved continuation of the protocol during 22 July 2009 meeting, for the following sites: Naval Hospital Oak Harbor and Naval Hospital Bremerton. Approval expires 22 July 2010.
- U.S. Army Medical Research and Material Command (USAMRMC), Human Subjects Research Review Board approved the subject protocol on 16 November 2007. Human Research Protections Office (HRPO) continuing review for 2009 is still waiting on Naval Medical Center San Diego to release the approval letter from 22 July 2009 IRB meeting.
- 3-Party CRDA between Naval Hospital Oak Harbor / Naval Hospital Bremerton and TRUE Research Foundation and Oregon Health & Science University expires 27 October 2009. Renewal is not anticipated since TRUE Research Foundation is no longer a participant in the project.
- MOU between Madigan Army Medical Center and Naval Hospital Bremerton MCHJ-120-08 supersedes MCHJ-131-04. Effective period 25 November 2008 – 24 November 2013.
- DoD Assurance for Naval Hospital Bremerton, DoD N40027, expires 30 January 2010.
- Changes to Staff in 2009 at Bremerton. Dr Ronald Dommermuth moved from the role of medical monitor to Associate Investigator (AI). CAPT Robert Martin, MD took over medical monitor duties. LCDR Jeffrey Martens, MD and Dr Lauren Gist joined the study as AIs at Bremerton. Memorandums with staff updates were submitted to Chair, NMCSD IRB in February 2009.
- CDR Victoria Crescenzi, MD received initial TeleEcho Training on December 14-15, 2004.
- Dr Ronald Dommermuth received initial TeleEcho Training on March 15-16, 2005.
- LCDR Jeffrey Martens, MD received initial TeleEcho Training on December 18-19, 2007.
- Dr Lauren Gist received initial TeleEcho Training on January 14-15, 2008.

- CITI - The Protection in Human Research Subjects Training is current for all site investigators.
- Curriculum Vitae are current for all site investigators.
- Drs Sahn, Puntel, & Kinney privileges are current.
- Bremerton's TeleEcho System is certified and registered on the USAMITC Bridge to Madigan's outside gatekeeper. Since the Navy has not made the same network upgrades, the Polycom 512 is still operational; however, a bad Polycom power supply is preventing the codec from dialing out. In addition, the Navy will make the same network upgrade as USAMITC at which time the Polycom 512 will become obsolete. A new power supply will be purchased to prevent an interruption in service until the VTC system is modernized.
- A total of 3 subjects were enrolled from NHB, of which 3 were in 2009. We believe enrollment was low in 2008-2009 due to (1) Delays by Naval Medical Center San Diego IRB; (2) Periods of network outage while transferring communications to MEDNET in 2008; (3) Service interruption at Madigan caused by USAMITC's network upgrade in 2009; and (4) Bad Polycom power supply. No SAE/AE to report.
- Dr Puntel holds monthly cardiac clinics at NHB. Local Investigators rotate during the clinic to retain proficiency performing supervised echocardiograms. Three month follow-up conventional echocardiography will be performed by COL Robert A. Puntel, MD during these outpatient cardiac clinics held at Bremerton.

Alaska Native Medical Center (ANMC), Anchorage, AK

- Annual Continuing Review of site-specific protocol. Alaska Area IRB issued continuing approval in a memo dated 18 August 2009. Approval expires 28 July 2010.
- Alaska Native Tribal Health Consortium (ANTHC) Board of Directors reviewed and approved the protocol on 5 December 2008.
- U.S. Army Medical Research and Material Command (USAMRMC), Human Subjects Research Review Board approved the subject protocol on 1 November 2007. Human Research Protections Office (HRPO) continuing review acceptance on 8 September 2009.
- Changes to staff in 2009. Dr Haitham Salman is no longer at Alaska Native Medical Center. An administrative memo to update personnel will be submitted to the Alaska Area IRB to remove Dr Salman as an Associate Investigator in the study.
- Drs Engel and Gonzales received initial TeleEcho Training on April 10-12, 2004.
- CITI - The Protection in Human Research Subjects Training: Dr Gonzales overdue refresher training.
- Curriculum Vitae are current for all site investigators.
- Drs Sahn, Puntel, & Kinney privileges are current.
- Alaska Native's TeleEcho System is certified and registered on the USAMITC Bridge to the USAMITC outside gatekeeper. It was fully operational with an active IP address until the ANMC network upgrade in 2008 that made the Polycom 512 obsolete. As a work around, Dr Engel arranges with IMD to bring a borrowed Polycom VSX7000 when needed for a TeleEcho.
- Dr Engel enrolled a training model on 4 March 2009 to test the telemedicine lines and receive TeleEcho Refresher Training.
- ANMC is ready to enroll subjects. We believe enrollment was low in 2008-2009 due to (1) Staff shortage and Alaska outreach travel; (2) Lack of a dedicated TeleEcho VTC system available for investigator to use in 2008-2009; (3) Periods of network outage while

transferring communications to MEDNET in 2008; and (4) Service interruption at Madigan caused by USAMITC's network upgrade in 2009. No SAE/AE to report.

3<sup>rd</sup> Medical Group (3MDG), Elmendorf AFB, AK

- Annual Continuing Review of site-specific protocol. The subject protocol received continuing approval from the 60<sup>th</sup> Medical Group IRB on 8 September 2008. Approval expires 1 May 2009. The current continuing review has been in work since April 2009. The previous PI left the hospital and a new PI, MAJ Randall Twenhafel, MD was recruited. His package was submitted on 2 Jun 2009 to the Compliance Department at Travis AFB. The continuing review was held on 6 July 2009. The TeleEcho protocol was approved for continuing review and MAJ Twenhafel was approved as the new principal investigator; however, until they receive the updated IRB Agreement all approval letters and consent forms will be withheld. All approved documents will be forwarded to HRPO as soon as they are released by the 60<sup>th</sup> Medical Group IRB.
- U.S. Army Medical Research and Material Command (USAMRMC), Office of Research Protections (ORP), Human Research Protection Office (HRPO) approved the protocol on 20 January 2009.
- Changes to staff in 2009. MAJ Laura Peterson, MD separated from the United States Air Force and removed as Principal Investigator. MAJ Randall Twenhafel, MD was approved by 60<sup>th</sup> MDG IRB as the new Principal Investigator on 6 July 2009. MAJ Heather Jones, MD just left Elmendorf and a search for a new medical monitor has begun. The change in staff will be updated to IRB and HRPO as soon as a new replacement is found.
- MAJ Randall Twenhafel, MD will be scheduled for TeleEcho Training once telemedicine lines have been authorized.
- CITI - The Protection in Human Research Subjects Training is now an annual event for the Air Force. Local staff is current but Madigan's project team will need to complete refresher training on the shorter Air Force cycle.
- Curriculum Vitae are current for all site investigators.
- Drs Sahn, Puntel, & Kinney privileges are current.
- 3MDG received all necessary components for the TeleEcho System; however, they will not be upgraded to the MicroMaxx or new VTC until telemedicine lines have been authorized.
- Connectivity with 3MDG has encountered numerous roadblocks. Including being routed all the way to HQ AF Communications Agency in Washington, D.C. After review, HQ AF Communications Agency recognized no major issues and fielded the issue back to HQ PACAF. Previous 3MDG CIO, CPT Sorrells, still has some concerns with connecting the TeleEcho System to his network. He was supposed to work with the technical consultants and network administrators to resolve the concerns but nothing resulted. The current 3MDG Support Flight commander, MAJ Jeffrey Eyink, states that the clinic does not have any VTC capability on the network because they don't have Authorization To Operate (ATO) for connect. Currently the only vendor that the AF will allow them to use is the Polycom since it is JTIC certified. He is willing to try ISDN connection as a work around; however, the telephone switch in the hospital doesn't have any more ISDN capabilities. He can "get with our facilities to see if 3 CS can purchase another card for the switch".
- 3MDG will be ready to enroll subjects once the IRB Agreement has been turned in, a new medical monitor is recruited, the PI attends the TeleEcho Training Seminar, and telemedicine lines are established. Anticipated date: Spring 2010.

Bayne-Jones Army Community Hospital (BJACH), Ft. Polk, LA

- Annual Continuing Review of site-specific protocol. The Brooke Army Medical Center (BAMC) IRB approved continuation of the protocol on 22 April 2009. Approval expires March 2010.
- U.S. Army Medical Research and Material Command (USAMRMC), Office of Research Protections (ORP), Human Research Protection Office (HRPO) approved the subject protocol on 29 January 2009.
- No changes to staff in 2009.
- CITI - The Protection in Human Research Subjects Training is current for all site investigators.
- Data Use Agreement and Waiver of Authorization complete and in place.

Blanchfield Army Community Hospital, Ft. Campbell, KY

- Site-specific protocol closed due to no current Principal Investigator. The original PI, Dr. Robert Moore, is no longer at Blanchfield ACH. CPT Carol J. Rowe, MD volunteered to be PI but then deployed. Once CPT Rowe meets IRB requirements and finishes CITI training, the protocol will be resubmitted to Eisenhower Army Medical Center IRB.
- Data Use Agreement and Waiver of Authorization complete and approved.
- Original protocol documents submitted to HRPO but are no longer current. A current site specific protocol will be submitted to the HRPO for final approval once the new PI has completed necessary requirements.

Yukon-Kuskokwin Health Corporation (YKHC), Bethel, AK

- This facility has been holding off participating in the study due to staff constraints. They are now expressing interest. Ellen Hodges a Family Practitioner is the Chief of Staff and she is very interested in this study. There are also 5 pediatricians on staff all of whom are excited about the program. Dr Brauner one visiting Pediatric Cardiologist to Bethel from Anchorage (Dr Kinney knows him well) was against the study in the past but has recently sold his practice to Seattle Children's. Scott Wellman the other Pediatric Cardiologist would welcome the study based on previous conversations. Funding for a complete TeleEcho System is needed in order to make it happen.

**2- An update on individuals trained, to perform echocardiograms on newborn infants; number of days, and the dates of training.**

Summary February 2004 – December 2008:

- 20 TeleEcho Training Seminars
- 40 days of training
- 37 Providers trained to perform supervised echocardiograms
- CME Credits Offered: 224
- CME Credits Assigned: 224

14 Category-1 CME credits were offered for each trainee attending the TeleEcho Training Seminar held through September 2008.

## **Learning Objectives**

Initial training for pediatricians, family physicians or nurse practitioners for the Tele-ECHO project. This is held at Madigan Army Medical Center in the clinic and the NICU.

Learning objectives:

1. Learners will understand the physical basis of ultrasonography including 2-dimensional imaging and Doppler ultrasound utilizing both, the portable SonoSite ultrasound machine as well as standard ATL or HP echocardiography machines.
  2. Learners will learn and demonstrate competence in performing the complete transthoracic echocardiogram with practice and demonstration on consented infants at Madigan AMC to include 2-dimensional views, color and spectral Doppler interrogation, and m-mode echocardiography.
  3. Learners will discuss and demonstrate understanding of common congenital cardiac defects and their appearance on echocardiography as well as their clinical presentation using live patients as available, as well as internet, text, slides, and videotaped cases.
  4. Learners will discuss and demonstrate understanding of the clinical management of congenital cardiac lesions.
  5. Learners will review Human Subject issues and consenting families, as well as data entry, internet systems for data collection, and the equipment used to transmit and record the tele-echo images.
  6. Learners will demonstrate competence with Protection of Human Research Subjects by completing CITI online training before attending training.
  7. Learners will demonstrate proficiency by performing satisfactorily a minimum of 5 echocardiograms only with verbal guidance from the instructor.
- February 21 – February 28, 2004  
CPT Ronald Wells, MD, BACH
- March 24 – March 25, 2004  
LCDR Andrea Donalty, MD, NHOH
- March 29 – March 31, 2004  
CPT Athena Stoyas, MD, WACH
- April 10 – April 12, 2004  
Dr. Michael Engel, ANMC  
Dr. Calle Gonzales, ANMC  
Dr. Haitham Salman, ANMC
- April 17 – April 19, 2004  
CDR Karie Andersen, MD, NHB  
LCDR Rose Dieffenbach, MD, NHB
- September 29 – September 30, 2004  
CPT Robert Warner, MD, WACH

- December 9 – December 10, 2004  
MAJ Donald Lane, MD, 3MDG  
COL David Estroff, MD, MAMC  
CPT Katy Gibson, MD, MAMC (Resident)
  
- December 14 – December 15, 2004  
CDR Victoria Crescenzi, MD, NHB  
CPT Katy Gibson, MD, MAMC (Resident)
  
- January 11 – January 12, 2005  
MAJ Nola McManus, MD, 3MDG  
MAJ John Harvey, MD, MAMC
  
- March 15 – March 16, 2005  
LCDR Christopher Westbrook, MD, NHB  
CDR Ronald Dommermuth, MD, NHB  
Dr Daisuke Kobayashi
  
- May 17 – May 18, 2005  
Cathy Binder, NP, BACH
  
- October 20 – October 21, 2005  
CPT Reaches Richards, MD, WACH  
CPT Rebecca Garfinkle, MD, BACH  
LT David Eigner, MD, MAMC (Resident)
  
- January 24 – January 25, 2006  
MAJ Laura Peterson, MD, 3MDG
  
- August 15 – August 16, 2006  
CPT Steven Jay, MD, BACH  
LT Bonnie Geneman, MD, MAMC (Resident)  
LT Damien Powell, MD, MAMC (Resident)
  
- December 18 – December 19, 2007  
LCDR Jeff Martens, MD, NHB  
Dr Ruth Faircloth, MD, MAMC (Resident)
  
- January 14 – January 15, 2008  
CPT Peter Vickerman, MD, BACH  
Dr Lauren Gist, MD, NHB
  
- April 8 – April 9, 2008  
LCDR Jeff McClellen, MD, NHB  
CPT Dr Johnson Isaac, MD, MAMC

- May 6 – May 7, 2008  
CPT Rebeckah Burns, MD, BACH
- September 11, 2008  
Dr Ronald Williams, MD, MAMC (PCS to WACH)  
Margaret Williams, PNP, MAMC (PCS to WACH)
- December 9 – December 10, 2008  
LCDR Harlan Dorey, MD, NHOH

### **3- An update of the infrastructure plans- to bring up site connections.**

#### Madigan Army Medical Center (MAMC), Ft. Lewis, WA

- Madigan is certified and registered on the United States Army Medical Information Technology Center (USAMITC) Bridge and fully operational on the MEDNET. The transition took longer than anticipated causing 3 months lapse in data collection in 2008.
- Test calls demonstrate very good audio and video quality.
- USAMITC forgot to notify anyone in the TeleEcho Project regarding a planned network upgrade. Any TeleEcho Polycom model 512 or FX on the MEDNET became incompatible due to the Codian that replaced the RADVision. 1-3 months of service interruption, site dependent, was caused due to this oversight in 2009. The service interruption could have been longer; however, Madigan Ophthalmology had a Tandberg 3000MXP not in use and agreed to loan it to the TeleEcho Project until a replacement was purchased or until they needed the equipment.
- The older SonoSite ultrasound system has been exchanged for the newer all digital MicroMaxx.
- A Tandberg Edge 95MXP with PrecisionHD camera and a flat screen monitor will replace the outdated Polycom ViewStation FX and 19" monitor. We anticipate delivery of equipment by beginning of November 2009.

#### Bassett Army Community Hospital (BACH), Ft. Wainwright, AK

- Bassett's TeleEcho System is certified and registered on the USAMITC Bridge and was fully operational on the MEDNET until the USAMITC network upgrade at Bassett in January 2009 made the Polycom 512 obsolete. As a work around, IMD brings a borrowed VTC to the mother-baby-unit when needed for a TeleEcho.
- Test calls demonstrate very good audio and video quality.
- The older SonoSite ultrasound system has been exchanged for the newer all digital MicroMaxx.
- A Tandberg Edge 95MXP with PrecisionHD camera and a flat screen monitor will replace the outdated Polycom ViewStation FX and 19" monitor. We anticipate delivery of equipment to Madigan by beginning of November 2009.

#### Weed Army Community Hospital (WACH), Ft. Irwin, CA

- Weed's TeleEcho System is certified and registered on the USAMITC Bridge and was fully operational on the MEDNET until the USAMITC network upgrade in 2009 that made the Polycom 512 obsolete. As a work around, IMD installed a newer model Polycom until a permanent upgrade could be procured.
- Test calls demonstrate very good audio and video quality.
- The older SonoSite ultrasound system has been exchanged for the newer all digital MicroMaxx.
- A Tandberg Edge 95MXP with PrecisionHD camera and a flat screen monitor will replace the outdated Polycom ViewStation FX and 19" monitor. We anticipate delivery of equipment to Madigan by beginning of November 2009.

#### Naval Hospital Oak Harbor (NHOH), Oak Harbor, WA

- Oak Harbor's TeleEcho System is certified and registered on the USAMITC Bridge to Madigan's outside gatekeeper. Since the Navy has not made the same network upgrades, the Polycom 512 is still operational; however, a bad Polycom power supply is preventing the codec from dialing out. In addition, the Navy will make the same network upgrade as USAMITC at which time the Polycom 512 will become obsolete. A new power supply will be purchased to prevent an interruption in service until the VTC system is modernized.
- Test calls demonstrate very good audio and video quality; however, the images are more pixilated than those sent from within the MEDNET.
- The older SonoSite ultrasound system has been exchanged for the newer all digital MicroMaxx.
- A Tandberg Edge 95MXP with PrecisionHD camera and a flat screen monitor will replace the outdated Polycom ViewStation FX and 19" monitor. We anticipate delivery of equipment to Madigan by beginning of November 2009.

#### Naval Hospital Bremerton (NHB), Bremerton, WA

- Bremerton's TeleEcho System is certified and registered on the USAMITC Bridge to Madigan's outside gatekeeper. Since the Navy has not made the same network upgrades, the Polycom 512 is still operational; however, a bad Polycom power supply is preventing the codec from dialing out. In addition, the Navy will make the same network upgrade as USAMITC at which time the Polycom 512 will become obsolete. A new power supply will be purchased to prevent an interruption in service until the VTC system is modernized.
- Test calls demonstrate very good audio and video quality; however, the images are more pixilated than those sent from within the MEDNET.
- The older SonoSite ultrasound system has been exchanged for the newer all digital MicroMaxx.
- A Tandberg Edge 95MXP with PrecisionHD camera and a flat screen monitor will replace the outdated Polycom ViewStation FX and 19" monitor. We anticipate delivery of equipment to Madigan by beginning of November 2009.

#### Alaska Native Medical Center (ANMC), Anchorage, AK

- Alaska Native's TeleEcho System is certified and registered on the USAMITC Bridge to the USAMITC outside gatekeeper. Routing the call through the USAMITC Bridge slows the transmission speed considerably. Until this issue is resolved, ANMC will continue to keep their IP (Internet Protocol) connection active.
- The system was fully operational with an active IP address until the ANMC network upgrade in 2008 made the Polycom 512 obsolete. As a work around, Dr Engel arranges with IMD to bring a borrowed Polycom VSX7000 when needed for a TeleEcho. The VSX7000 port settings allow for 100FULL vs. 10FULL allowing for increase video quality.
- The older SonoSite ultrasound system has been exchanged for the newer all digital MicroMaxx.
- A Tandberg Edge 95MXP with PrecisionHD camera and a flat screen monitor will replace the outdated Polycom ViewStation FX and 19" monitor. We anticipate delivery of equipment to Madigan by beginning of November 2009.

#### 3<sup>rd</sup> Medical Group (3MDG), Elmendorf AFB, AK

- 3MDG received all necessary components for the TeleEcho System. Connectivity with 3MDG has encountered numerous roadblocks. Including being routed all the way to HQ AF Communications Agency in Washington, D.C. After review, HQ AF Communications Agency recognized no major issues and fielded the issue back to HQ PACAF. Previous 3MDG CIO, CPT Sorrells, has some concerns with connecting the TeleEcho System to their local area network. He explained that the Air Force network is more stringent than the Army's. His biggest concern is that 3 Polycom port ranges are flagged as potential threats according to the Air Force Approval Matrix. Two of the port requests are Yellow (medium threat) and one is Red (High threat). He will work with the technical consultants and network administrators to resolve the concerns. Additionally, CPT Sorrells explained this is a bad time for adding new systems to the network; it may take quite a bit of time.
- We assumed that since the MEDNET is an approved VTC network for the DoD it should speed up connectivity approvals with the Air Force but we later learned that the Air Force developed a policy not to do VTC over IP.
- The current 3MDG Support Flight commander, MAJ Jeffrey Eyink, states that the clinic does not have any VTC capability on the network because they don't have Authorization To Operate (ATO) for connect. Currently the only vendor that the AF will allow them to use is the Polycom since it is JTIC certified. He is willing to try ISDN connection as a work around; however, the telephone switch in the hospital doesn't have any more ISDN capabilities. He can "get with our facilities to see if 3 CS can purchase another card for the switch".
- The older SonoSite ultrasound system has not been exchanged for the newer all digital MicroMaxx. The swap out will occur once the Air Force solves the connectivity issue.
- A Tandberg Edge 95MXP with PrecisionHD camera and a flat screen monitor will replace the outdated Polycom ViewStation FX and 19" monitor. We anticipate delivery of equipment to Madigan by beginning of November 2009 but we will not send to Elmendorf until we receive a guarantee that it will be allowed connectivity.

### Yukon-Kuskokwin Health Corporation (YKHC), Bethel, AK

- This facility has been holding off participating in the study due to staff constraints. They are now expressing interest. Ellen Hodges a Family Practitioner is the Chief of Staff and she is very interested in this study. There are also 5 pediatricians on staff all of whom are excited about the program. Dr Brauner one visiting Pediatric Cardiologist to Bethel from Anchorage (Dr Kinney knows him well) was against the study in the past but has recently sold his practice to Seattle Children's. Scott Wellman the other Pediatric Cardiologist would welcome the study based on previous conversations. Funding for a complete TeleEcho System is needed in order to make it happen.

## **4- Communications Infrastructure**

Due to the security environment in the Army, all VTC over IP are in process of removal from the NIPRNET. United States Army Medical Information Technology Center (USAMITC) now provides the infrastructure for a single Army medical network (MEDNET) operating environment that enables corporate information sharing and centralized management. The creation of MEDNET or USAMITC Video Network Center Bridge allows for a secure and efficient means of providing channels for video teleconferencing for DoD and non-DoD facilities.

We have transitioned our communication infrastructure from the NIPRNET to the MEDNET. The necessary hardware is already in place at the Army facilities. Non-Army facilities will be able to connect by registering their IP addresses with the outside gatekeeper at either Madigan or USAMITC. Once registered, the firewall will allow calls between the approved and authorized systems. The transition took longer than anticipated causing 3 months lapse in data collection.

More time was lost when USAMITC forgot to notify personnel in the TeleEcho Project regarding a planned network upgrade. USAMITC was aware that any TeleEcho Polycom model 512 or FX on the MEDNET would become incompatible due to replacing the RADVision with a Codian. Service interruption between January and March 2009, depending on the site, was experienced due to this oversight. The service interruption could have been longer had a loaner VTC unit not been found. Madigan Ophthalmology had a Tandberg 3000MXP not currently in use and agreed to loan it to the TeleEcho Project until a replacement was purchased or until they needed the equipment. Once the Tandberg was certified and registered with USAMITC, Madigan was available for enrollment again.

Overall technical delays and difficulties are expected to decrease with modern VTC equipment and support from the experienced staff at USAMITC. Standardizing to Tandberg codecs and utilizing the Army's MEDNET infrastructure and security help ensure continued stability, sustainability, and viability of the TeleEcho Project.

## **5- New Scanners Installed**

We have completed the replacement of the SonoHeart Elite® systems with the new Digital system the MicroMaxx®. The MicroMaxx® system has better color Doppler quality and the phased array as opposed to a linear curved array transducer. This allows imaging at runs at between 8.5 and 11MHZ with higher resolution and considerably improved color Doppler flow

visualization. In addition, the MicroMaxx digital images transmit with higher quality resulting in a clearer image at the reading sites.

The TeleEcho Project is currently operating with borrowed VTC equipment and outdated VTC codecs. Some sites can not currently connect to Madigan due to the outdated VTC codec. Tandberg VTC equipment is required for modernization. The original codecs, Polycom ViewStation FX and Polycom ViewStation 512s, are over 6 years old. When the Army updated from RADVision to Codian in 2009, the codecs in use with the TeleEcho Project no longer worked on the Army's network. The older VTC technology is incompatible with newer more secure network technologies. The Department of Army is in process of standardizing to Tandberg codecs. By purchasing standardized equipment, Information Management Division (IMD) and U.S. Army Medical Information Technology Center (USAMITC) can provide technical support and expertise. Funding is provided through AMEDD Advanced Medical Technology Initiative (AAMTI) FY09, APC-T690 Special Fund for TeleEcho. The Capital Equipment Program (CEEP) purchase request was submitted on 21 July 2009. Once it arrives, the new equipment will be distributed to sites actively enrolling subjects.

## **KEY RESEARCH ACCOMPLISHMENTS:**

- In January 2008, a 3 day old male at Bassett Army Community Hospital in Fairbanks, AK was diagnosed with coarctation, transported, and underwent surgery before any serious symptoms developed using the TeleEcho System. The on-call family practitioner at Bassett could not appreciate femoral pulses on the subject while in the nursery. Differential BP's showed a 20-30 point drop in BP's from upper extremity to lower extremity. The investigator could not appreciate distal pulses the morning of the TeleEcho transmission. COL Robert Puntel, MD reading pediatric cardiologist at Madigan recognized a moderate coarctation with a gradient of 35mmHg and recommended the infant transfer to Children's in Seattle for probable surgical repair within the next 24-48 hours. The infant is now doing well.
- In November 2008, a 2 day old male at Bassett Army Community Hospital in Fairbanks, AK was diagnosed with a Tetralogy variant, VSD with overriding aorta and pulmonary atresia using the TeleEcho System. The infant was asymptomatic and in process of being discharged when the Principal Investigator at Bassett recognized a murmur and requested a TeleEcho before sending the infant home over a long holiday weekend. COL James Kinney, MD reading pediatric cardiologist at Madigan quickly recognized a VSD with overriding aorta suggesting a Tetralogy variant; pulmonary arteries were not identified. He recommended follow up immediately with Dr Wellman at Providence in Anchorage and emergent catheterization. The infant is now doing well.
- On 11 September 2009, after the period of this report, COL Kinney and COL Puntel performed a TeleEcho study on a 4 week old male at Naval Hospital Oak Harbor who had been given the diagnosis of an Atrial Septal Defect by a civilian institution. However, a significant pulmonary valve stenosis was found that had not been previously noted, likely due to the natural decrease in pulmonary vascular resistance. This new diagnosis will require early intervention and would have been delayed without the review using the TeleEcho System. The infant will be further assessed at the new Oak Harbor cardiac clinic follow-up within a week of this study.
- TeleEcho has recognized an overall decrease in unnecessary transports as once the physician/investigator has reliable information on the patient, it affects treatment.
- The telemedicine system has also been useful in cases that did not qualify for the study due to the subject's age or condition. Eliminating unnecessary transport from Whidbey Island to Madigan Army Medical Center and eliminating the patient to additional exposure to x-ray and MRI.

## **REPORTABLE OUTCOMES:**

### **1- Funding Awards**

COL Robert Puntel, principal investigator at Madigan, applied the TeleEcho Project for and was selected to receive AAMTI FY09 funding from Telemedicine & Advanced Technology Research Center (TATRC). The additional funds are being used to extend the life of the TeleEcho Project in order to demonstrate the effectiveness of the TeleEcho System Virtual User Interface, software which allows the reading pediatric cardiologist to control the sending site's ultrasound panel. The Virtual User Interface will be installed and tested during future TeleEcho studies. AAMTI FY09 funding is being used to continue the project through 2010 by providing the salary for a Project Coordinator and VTC equipment modernization.

### **2- Abstract & Poster Presentation**

An abstract and poster titled, "The Next Step in TeleMedicine Ultrasound for Congenital Heart Disease: Live TeleEcho with Virtual User Interface" was on display at the Congressionally Directed Medical Research Program's Military Health Research Forum 2009 in Kansas City, MO.

### **3- Virtual User Interface**

A software program has been developed by SonoSite which allows access to the MicroMaxx control panel through a secure IP connection. Remote access allows the reading pediatric cardiologist to operate any button or knob on the control panel of the MicroMaxx® ultrasound scanner being used to study patients at the distant site. Since this is a fully digital system, the remote control allows optimization of more controls of Doppler parameter control, color Doppler quality, and directed sampling for M mode and spectral Doppler recordings.

**Methods:** The Virtual User Interface (VUI) communicates between the far site MicroMaxx® and the supervising expert's computer through secure IP connections. It allows interactive control of the far site MicroMaxx® panel and keyboard by the cardiologist at the supervising site with rapid response. The cardiologist uses their computer to control all other features of the examination including color and spectral Doppler analysis, m-mode, adjustment of PRF or gain, and saving or reviewing clips.

**Results:** The software has stable, consistent and fast performance over the Internet, is easy to install, easy to operate and feels truly interactive to the remote supervisor. VUI allows the expert at the medical center to peruse the echocardiogram image with more accurately placed color and spectral Doppler box and cursors; while allowing the provider performing the echocardiogram at far sites to focus only on directing the transducer and the 2-dimensional image. In its first test implementations, VUI demonstrates the capability of optimized quality and shortened exam time for neonatal tele-echocardiographic examinations in first test implementations.

**Conclusions:** Remote control operation of the handheld ultrasound system appears to optimize the TeleEcho exam and facilitates supervision and interpretation of images with a simultaneous live videoconferencing link. Use of Virtual User Interface is expected to decrease TeleEcho examination call time. This technology represents the next step in pediatric telemedicine.

#### **4- Database**

An Access Database was created to enter and track subject information for data analysis by Dr Grigsby's staff. The project received control of the database on 30 July 2009. The website domain initially created to facilitate data entry was never utilized. While operational at one point in time, it was allowed to lapse due to the long period of inactivity while the research protocol was under review. Up till this point, studies have been collected manually awaiting availability of the database. Entry of past studies will be entered as will all future studies.

## **CONCLUSION:**

TeleEcho has many benefits for the military medical community. It can improve access and quality of care while reducing cost. TeleEcho improves access to care by providing a diagnostic tool that is available only at medical centers. Currently, MEDDACs do not have the equipment or trained personnel to perform pediatric echocardiogram or ECHO. Patients requiring an ECHO must be transferred to a medical center. A primary care provider can perform the TeleEcho with remote supervision of the study by the expert at the medical center, thus the time and resources of cardiologists can also be more efficiently utilized. TeleEcho remote diagnosis will allow Tricare to recapture medical evacuation costs. Tricare spends \$5-8K per urgent medical evacuation from our regional Navy bases to Madigan Army Medical Center (MAMC) for ECHOs. This occurs approximately twice per week. The majority of ECHOs show that non-emergent transportation is appropriate. Medical air evacuation from Alaska costs between \$20-40k per transport.

Monetary savings for necessary transports occur more efficiently by routing a sick patient directly to the appropriate center once a diagnosis has been made. Sick infants born at in Alaska with confirmed heart disease via TeleEcho can, and have been, transported directly to Seattle Children's Hospital for surgery instead of routing through MAMC and then back to Seattle Children's Hospital. Thus, TeleEcho offers cost savings and improved quality and timing of care for the patient and family.

TeleEcho improves the quality of care by reducing parent stress. If no cardiac defect is found using the TeleEcho system, the infant will not require the often extreme duress of an unnecessary transport. The parent assigned downrange, can focus on the mission and know their dependents are receiving the best care possible. This technology, especially the remote control of the study via a trackball software upgrade in our study future, will be a tool for potential use in the battlefield for ECHO as well as emergency medical ultrasound use for acute injury triage purposes.

Numerous roadblocks were experienced that slowed down progression on the TeleEcho Project. The fact it is a multi-site research program slowed progress, especially for Navy hospitals. As a research protocol, the study requires IRB review within a 12 month period. Naval Medical Center San Diego reviews on a 10 month cycle; yet it continually takes 4 plus months before the continuing review approval letter and informed consent documents are returned to the Principal Investigators and Project Coordinator. In addition to delays by site specific reviews, the turn over and deployment rotations of investigators slowed down enrollment. On average, it takes 6 months to recruit a new investigator, have them meet all IRB requirements, receive IRB approval, and train them on TeleEcho. During this period of recruitment, review, and training the investigator cannot enroll subjects. This is especially significant when working within a limited time frame for enrollment.

Technical issues were a second major roadblock experienced throughout the study period. Issues ranged initially from Information Management Division (IMD) requiring a DITSCAP then DIACAP in order to keep TeleEcho communication operational. Necessary security and network upgrades within the Army caused delays as when IMD "forgot" about the project when USAMTIC upgraded the network in early 2009 causing the TeleEcho Polycom codecs to be "kicked" off the network. The process to procure new equipment has been slow though once received should move quickly. Technical problems are not unique to the Army as civilian

hospitals and the Air Force have had their own experiences. Alaska Native Health Center is a civilian facility and cannot connect to Madigan's outside gatekeeper. In order to conduct a TeleEcho at Madigan, the call must first go to the outside gatekeeper at USAMITC in San Antonio, TX then bounce back to Madigan in Tacoma, WA. The end effect is slower audio and video transmission of the cardiac images. The Air Force site at Elmendorf AFB has not been able to activate a telemedicine line from Alaska to Madigan. Current command support is pushing for the service to be available but the Air Force does not allow VTC over IP and they do not have a MEDNET node installed at Elmendorf. The new IMD is looking to see if they can connect via ISDN. If successful, it will offer an alternative method for connecting to TeleEcho.

The last major roadblock comes down to administrative support and funding. In order for the TeleEcho project to work successfully, funding for a full time project administrator is required to handle the daily operations of TeleEcho while the pediatric cardiologists focus on patient care. It would be beneficial for the project administrator to have IPA status in order to speak for the government. The project administrator provides administrative and procedural direction and assistance to the project staff at MAMC, OHSU, and the facilities within Western Regional Medical Command. A project administrator is essential in the planning, administrative coordination, approval process, implementation, and data management of the project. Also, essential to the continuation of TeleEcho as an outreach service is a schedule of funding for equipment modernization. The US Army Medical Material Agency TARA team has already offered support for major ultrasound equipment upgrades over \$100,000 but any expense under that would have to be processed through Madigan's CEEP manager. The program did receive AAMTI FY09 funding from TATRC that was used to modernize the VTC equipment; but there is no plan in place for future upgrades. AAMTI FY09 was also used for a personnel contract through end of 2010 but funding beyond that period has not been secured.

A shared goal amongst the investigators is the expansion of TeleEcho to other medical centers within the DoD and eventually civilian rural healthcare systems. A reproducible TeleEcho program could easily become standard of care within the military community but we require direction on how to proceed.

Progress had been slowed by the multiple human subject approvals required, investigator turnover and recruitment, placement of telemedicine systems on IP and conversion to the MEDNET. Only YKHC in Bethel, AK awaits entrance to the study; due to their remoteness, they chose to wait until new staff arrives and can be trained. The swap out the Elite® systems for the new MicroMaxx® scanners is complete in all but one site that will not yet allow connectivity. This year we plan to modernize the video teleconference equipment and deploy the Virtual User Interface so that we can continue enrolling subjects at all approved sites. TeleEcho Training Seminar will be re-instated so new investigators can receive initial echocardiography training. And of most importantly, continue to help infants in underserved regions for as long as we can.

Statement from David Sahn, MD, Principal Investigator:

This project has surmounted barriers including Firewalls- specific to the military, evolution of Handheld ultrasound with pre-planned upgrades from SonoSite, and has provided care to remote military and native Alaskan families and their children. It still represents cutting edge telemedicine and especially with the remote control of the ultrasound scanner- could be extended throughout the military- by creation of new hubs at major military installations.

A tenacious and dedicated group of physicians and Project coordinators in Oregon and at Madigan Army Medical Center at Fort Lewis in Tacoma- is proud to submit this as the final report of the Research initially funded by the PRMRP of the MRMC- and to developing future extensions of the Remote Neonatal Cardiac Diagnosis concept in Military and Civilian settings where access to Pediatric Cardiology Expertise is hampered by distance.

Statement from COL Robert A. Puntel, MD, Principal Investigator:

Our cardiology support of newborns in remote sites has been truly enhanced by this system. The accuracy of diagnoses has been 100% and we have expedited transfers or avoided unnecessary ones to assure best care. We have been able to provide the utmost in timely, accurate cardiac care for our patients.

Statement from COL James B. Kinney, MD, Associate Investigator:

The technology improved so rapidly that the conclusions were obvious. This resource should become standard of care for the US military.

## **REFERENCES:**

None

## **APPENDICES:**

### **Appendix 1: Acronyms**

AAIRB – Alaska Area Institutional Review Board

AAMTI – AMEDD Advanced Medical Technology Initiative

AES – Advanced Encryption Standard

AI – Associate Investigator

ANMC – Alaska Native Medical Center

ANTHC – Alaska Native Tribal Health Consortium

ATO – Authorization To Operate

BACH – Bassett Army Community Hospital

BJACH – Bayne-Jones Army Community Hospital

CCRP – Certified Clinical Research Professional

CDMRP – Congressionally Directed Medical Research Programs

CIRO – Clinical Investigation Regulatory Office

CITI – Collaborative IRB Training Initiative

CME – Continuing Medical Education

CRDA – Cooperative Research & Development Agreement

DAMD – Department of Army Medical Research & Development Command

DCI – Department of Clinical Investigation

DISN – Defense Information System Network

DIACAP – DoD Information Assurance Certification and Accreditation Process

DITSCAP – DoD Information Technology Security Certification and Accreditation Process

HIPPA - *Health Insurance Portability and Accountability Act of 1996 (HIPAA)*

HRPO – Human Research Protections Office

IATO – Interim Authorization To Operate

IRB – Institutional Review Board

ISDN – Integrated Services Digital Network

MAMC - Madigan Army Medical Center

MEDDAC – US Army Medical Department Activity

MEDCOM – Medical Command

MEDNET – Medical Network

NHB – Naval Hospital Bremerton  
NHOH – Naval Hospital Oak Harbor  
NIPRNET – Non-Secret IP Router Network

OHSU – Oregon Health & Science University

PI – Principle Investigator  
PRMRP – Peer Reviewed Medical Research Program

SOW – Statement of Work

TATRC - Telemedicine & Advanced Technology Research Center

USAMITC – U.S. Army Medical Information Technology Center  
USAMRMC – United States Army Medical Research & Material Command

VTC – Video Teleconference  
VUI – Virtual User Interface

WACH – Weed Army Community Hospital

YKHC – Yukon-Kuskokwim Health Corporation

## Appendix 2: Article published in the Mountaineer

### MAMC partnership delivers high-tech neonatal heart care

by Janis Kinney  
Public Affairs Assistant

Pediatric Cardiologists at Madigan Army Medical Center are providing some of the best medical care available to military beneficiaries while saving millions of dollars in the process. Since 2001, Madigan and Oregon Health & Science University have been managing a Department of Defense Neonatal Telemedicine Echocardiography Program with the help of a \$2 million grant from the U.S. Army Medical Research and Materiel Command at Fort Detrick, Md.

"This is going to be critically important in terms of saving millions of dollars, man hours, and unnecessary transports for fragile new-born babies," said Col. James Kinney, a pediatric cardiologist at Madigan.

The purpose of this program is to determine the impact of telemedicine based ultrasound for detecting or excluding heart disease in babies at remote military and Native American health care facilities. Health care providers involved in the program have made significant headway training network physicians, installing hardware, and solidifying the communication infrastructure to activate sites.

Although the program experienced some early obstacles because of post-Sept. 11 security requirements and security issues for logistics and transmission of patient-sensitive data, the program is now up and running with secure networks and a high grade of image transmission.

"Other tele-echo projects have been successful," Kinney explained. "But those are in hospitals where they use echo technicians with years of training. Our project provides equipment, training, and the physician to do the echo while supervised via poly-com equipment. This takes technology to places that don't have the equipment or technicians available."

This program does not just benefit Madigan, but also the patients in remote facilities in need of medical attention. Echocardiography has had major impacts in the management of newborn babies suspected of having congenital

See High-tech, Page 5

## Case managers dedicated to S

by Sharon D. Ayala  
Public Affairs Officer

After the start of the Global War on Terrorism in 2001, the roles of Army case managers grew exponentially. Shortly thereafter, Madigan Army Medical Center increased its civilian and military case management staff from two to 18 to ensure that all wounded Soldiers would have advocates working on their behalf.

Every week, anywhere from four to five Soldiers are medically evacuated to Madigan from the combat zone. Their injuries typically range from orthopedic injuries to traumatic brain injuries to medical conditions that cannot be treated in theater.

Retired Army Major Pam Birgenheier, deputy chief, Health Outcomes Division and supervisor case manager, oversees all case managers, whose job is to help those Soldiers get the medical care that they need.

"The case manager is the advocate for the patient," explained Birgenheier. "They facilitate and coordinate the plan of care by pulling all of the medical services together to ensure there is one plan of care for the Soldier."

Case managers know how important it is to quickly develop a relationship with Soldiers. Birgenheier said that all Soldiers who are medically evacuated are welcomed home at McChord Air Force Base by a case manager, a liaison from the Soldier's unit and a representative from Madigan's patient tracking. Those Soldiers are subsequently transferred to Madigan's emergency room for follow up treatment before being admitted.

"There are three case managers who provide case management support to all active duty inpatients with combat-related injuries," Birgenheier said. "They visit the service mem-



Guiselda Shank, a MAMC case manager, Tina Mandel. Case managers help Soldiers receive medical care.

ber daily to coordinate any follow up care and discharge planning. They also assist with getting out-of-state family members to the Soldier's bedside, if requested."

Medically evacuated Soldiers who are no

## RAVE REVIEWS! Program helps kids cope with parents' deployment

by Jeremy O'Bryan  
Mountaineer Editor



creates an environment that reduces the fear children have about their parents being deployed and the stress that follows.

"When a parent deploys, a child's sense of safety degrades," Callies explained. "When the stress of that increases, problem solving skills decrease, making it hard for a child to perform normal activities like paying attention in school, doing homework and doing chores."

The program is delivered in an average classroom setting, but usually in smaller-than-average groups. Children get six weeks of short lessons interspersed with homework

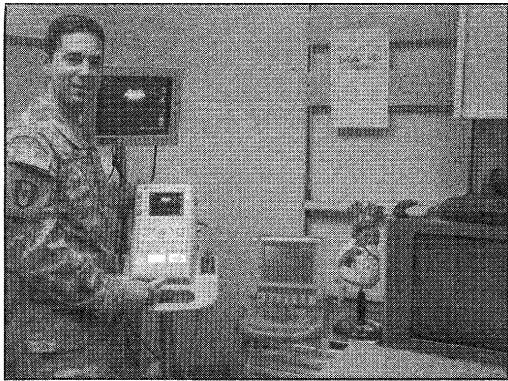


Photo by Janis Kinney

**Lt. Col. (Dr.) Robert Puntel, a pediatric cardiologist at Madigan, demonstrates how ultrasound equipment is used to discover heart problems in newborn babies.**

heart disease. The expensive, specialized equipment and significant expertise to adequately perform and interpret these studies usually is present only in major medical centers with a pediatric cardiologist on staff. Initial results of a National Multicenter Neonatal Telemedicine Echo Outcomes Study suggest that telemedicine-implemented diagnosis positively affects outcomes in infants suspected of having congenital heart disease.

"Many less urgent problems in neonates masquerade as heart disease," Kinney explained. "This program protects those infants from emergency transport from the isolated referring hospital when the symptoms are not of cardiac origin. We have now done about two dozen cases which have been critically reviewed for accuracy and we've been 100 percent accurate. Of those two dozen, six had heart disease, one needed serious surgery, and all of the patients had follow-up. The non-transport of those other 18 patients easily saved over \$100,000."

Kinney and Lt. Col. Robert Puntel, who is also a pediatric cardiologist, and the primary investigator for the project, train primary care practitioners to perform cardiac ultrasound exams with telemedicine supervision on newborn babies presumed to be at risk for heart disease. This enables them to diagnose heart disease in patients at remote facilities in a matter of minutes, improving outcomes. This study is targeted at military treatment facilities within Western Regional Medical Command. It also includes two large Alaska Native health care centers.

Participants from these other health care centers receive their quality training before they perform procedures on patients. Primary care practitioners come to Madigan for two days of preliminary instruction.

Through this program, physicians can develop expertise within caregivers who have previously not been able to perform these necessary exams, and will integrate the use of low-cost, yet high-performance hand-held ultrasound scanners, so as to provide the participating centers with new diagnostic health care capabilities.

The program has enabled 33 care givers, who are not cardiologists, to perform neonatal echo and has installed a high bandwidth telecommunications link using the military's internet infrastructure. MAMC is now overseeing neonatal echo exams from three military installations in the Northwest and in Alaska, as well as a large Alaska Native health center in Anchorage.

introduced to their assigned case manager. Soldiers who are case managed on an outpatient basis are either assigned to a medical holding unit or they are returned to their unit's rear detachment.

Capt. Nancy Davis is a registered nurse and case manager. She has served as an advocate for wounded Soldiers at Madigan since 2004. She is currently case managing 18 Soldiers, which, by the way, is well within the Army's standard of one case manager per 35 Soldiers. Davis, who works with acutely ill Soldiers, said that not only is her job very rewarding, but she also leaves work everyday wishing she had a few extra hours to do more for the Soldiers.

"My job truly gives me a perspective on the sacrifices that our Soldiers make for us. It makes me want to work that much harder for them to ensure that their outcome is the best that it can be," Davis said.

## Case Managers are Golden to Gulden

In 2005, Staff Sgt. Christopher Gulden, a National Guardsman, arrived back at Fort Lewis following a year-long deployment in Iraq. Once deactivated, Gulden returned back to his home state. But, after a little more than a year in Oregon, he returned to Madigan for rehabilitation for an elbow injury he sustained while deployed. Gulden said that having a case manager to provide him with direction was exactly what he needed the most.

"When I arrived back here I was pretty self-absorbed," Gulden said. "My case manager helped me to step back and get a clear view of what I needed to do to move ahead."

Gulden, who is a single father, credits his unit and three of Madigan's case managers for assisting in getting his 5-year-old daughter relocated to Washington State and enrolled in on-post day care while he finishes up his therapy.

"If it weren't for the three of them, I don't know where I would be," Gulden said.

The relationship between case managers and Soldiers is built on trust. And that trust, according to Birgenheier, comes more easily because all of Madigan's case managers have some connection with the military.

"A lot of times the Soldiers will see that some of us are civilian employees and they don't realize that we've been in the military. But, when they see a military plaque on the wall or something similar, it just opens the door for us," Birgenheier said.

Sgt. 1<sup>st</sup> Class Mike Alexander is assigned to Madigan's Medical Holding Company. His relationship with his case

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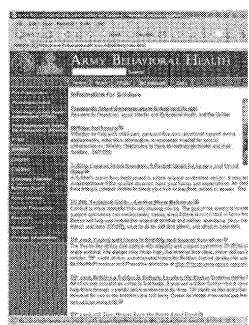
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## New behavioral health websit

What exactly is a Post-Deployment Health Reassessment? Where can I get help for my spouse who is having nightmares about experiences in combat? My buddy said he's thinking about committing suicide, what should I do?

Such questions come to the fore when Soldiers must deal with the stress of war. Now there is a new source for quick access to answers.

A new web site, entitled Army Behavioral Health, provides information for Soldiers, their families and other interested members of the public. Anyone can surf to it at <http://www.armybehavioralhealth.mil>.



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## Appendix 3: Abstract

### Media Center / Press Release

1. Li XK, Mack GK, Rusk RA, et al. Will a handheld ultrasound scanner be applicable for screening for heart abnormalities in newborns and children? *Journal of the American Society of Echocardiography* 2003; 16(10):1007-1014.
2. Sable C, Roca T, Gold J, et al. Live Transmission of Neonatal Echocardiograms from Underserved Areas: Accuracy, Patient Care, and Cost. *Telemedicine Journal* 1999; 5(4):339-347.
3. Webb CL, Waugh CL, Grigsby J, Berdusis K, Sahn DJ & Multicenter Telemedicine Collaborators Group. Impact of telemedicine on medical and financial outcomes in neonates with congenital heart disease. *Cardiology in the Young* 2001; 11(suppl 1):110-111.

### The Next Step in Telemedicine Ultrasound for Congenital Heart Disease: Live Video Teleconferencing with Remote Control of the Distant Scanner by the Expert Using a Virtual User Interface

**Author Block:** David J. Sahn<sup>1</sup>, James B Kinney<sup>2</sup>, Allegra Frank<sup>2</sup>, Robert Puntel<sup>2</sup>, Tomo Hasegawa<sup>3</sup>, Leo Catallo<sup>3</sup>. <sup>1</sup>Oregon Health & Science University, Portland, OR; <sup>2</sup>Madigan Army Medical Center, Fort Lewis, WA; <sup>3</sup>SonoSite Corporation, Bothell, WA

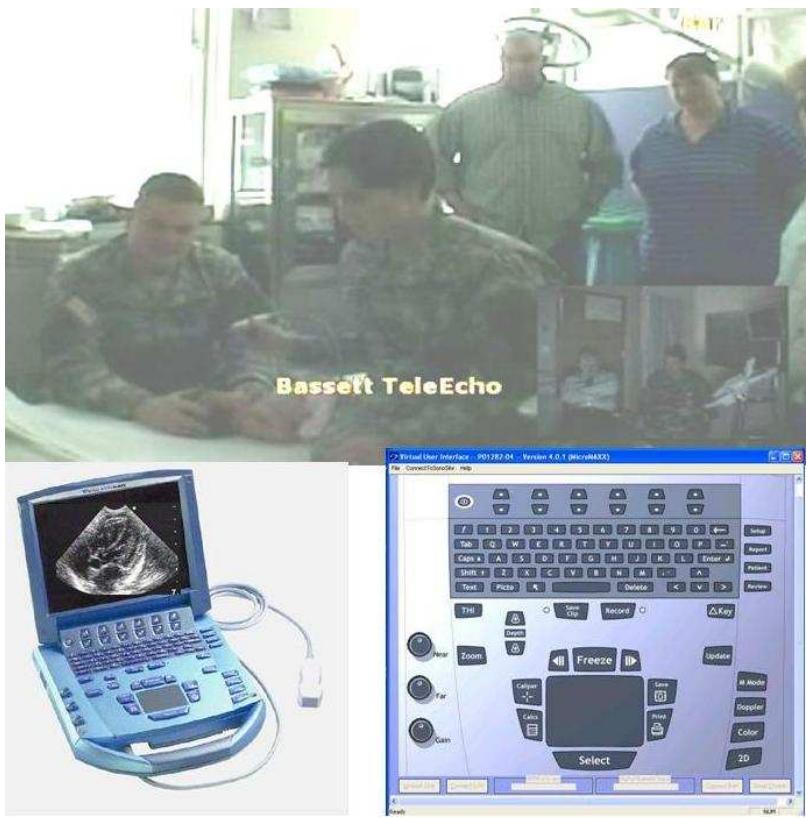
#### *Abstract:*

**Background:** Our US Department of Defense sponsored ultrasound telemedicine neonatal echocardiography program provides videoconferencing capability to remote military base hospitals and Alaska Native health centers for screening of babies for congenital heart disease.

**Methods:** We have now implemented remote control of the SonoSite MicroMAXX handheld system by the expert supervising and interpreting the study over IP connections and operating by a remote operating system, implemented via the Virtual User Interface PC application developed by SonoSite. Virtual User Interface allows control of all of the user accessible panel controls from the remote scanner by the expert with interactive and rapid response so that the physician or nurse performing the physical examination has only to direct the transducer while the remote supervising expert controls all other features of the examination, including turning on and off color Doppler, spectral analysis, adjustment of PRF, saving or reviewing clips.

**Results:** The software has stable, consistent and fast performance over the Internet, is easy to install, easy to operate and feels truly interactive to the remote supervisor. In its first test implementations, it appears to be capable of allowing optimized quality and shortened exam time for neonatal tele-echocardiographic examinations.

**Conclusions:** Remote control operation of the handheld ultrasound system appeared to optimize the echo exam and facilitate supervision and interpretation of images with a simultaneous videoconferencing link. We would suggest that this method represents the next step in pediatric telemedicine.



*Additional Consideration: YIA Competition:*

**Author Disclosure Information:** D.J. Sahn, SonoSite Corporation 5; A. Frank, None; R. Puntel, None; T. Hasegawa, SonoSite Corporation 3; L. Catallo, SonoSite Corporation 3.

## Appendix 4: Poster



# The Next Step in TeleMedicine Ultrasound for Congenital Heart Disease: Live TeleEcho with Virtual User Interface



**David J. Sahn<sup>1</sup>, Robert Puntel<sup>2</sup>, James B Kinney<sup>2</sup>, Allegra Frank<sup>2</sup>, Tomo Hasegawa<sup>3</sup>, Leo Catallo<sup>3</sup>, <sup>1</sup>Oregon Health & Science University, Portland, OR; <sup>2</sup>Madigan Army Medical Center, Fort Lewis, WA; <sup>3</sup>SonoSite Corporation, Bothell, WA**

### Background

The TeleEcho Project screens newborns for congenital heart disease by providing real-time supervision of echocardiograms over telemedicine lines. Pediatric cardiologists at Madigan Army Medical Center supervise live echocardiograms performed by pediatricians or nurse practitioners from MEDDACs and Alaska Native hospitals. The system includes an off-the-shelf portable ultrasound unit and video teleconferencing equipment.

Total of 37 TeleEcho trained providers at:

- 3rd Medical Group, Elmendorf AFB, AK
- Alaska Native Medical Center, Anchorage, AK
- Bassett Army Community Hospital, Ft Wainwright, AK
- Naval Hospital Bremerton, Bremerton, WA
- Naval Hospital Oak Harbor, Oak Harbor, WA
- Weed Army Community Hospital, Ft Irwin, CA

TeleEcho diagnosed cardiac abnormalities: ASD, PDA, PFO, PPS, VSD, coarctation and Tetralogy variants. Diagnosis confirmed 100% with follow-up conventional echocardiography. Coarctation and Tetralogy patients had successful cardiac surgery. 100 subjects enrolled.

Supervising sites have implemented remote control of the SonoSite MicroMaxx® keyboard via the Virtual User Interface application developed by SonoSite. FY 2009 funding from TATRC, Telemedicine & Advanced Technology Research Center, allows an upgrade of video teleconferencing equipment and deployment of the Virtual User Interface program at far sites.

### Methods

The Virtual User Interface communicates between the far site MicroMaxx® and the supervising expert's computer through secure IP connections. It allows interactive control of the far site MicroMaxx® panel and keyboard by the cardiologist at the supervising site with rapid response. The cardiologist uses their computer to control all other features of the examination including color and spectral Doppler analysis, m-mode, adjustment of PRF or gain, and saving or reviewing clips.



### Results

- ♦ Easy to install and operate.
- ♦ Stable, consistent and fast performance over the Internet.
- ♦ Allows the expert at the medical center to peruse the echocardiogram image with more accurately placed color and spectral Doppler boxes and cursors.
- ♦ Allows the provider performing the echocardiogram at far sites to focus only on directing the transducer and the 2-dimensional image.
- ♦ Demonstrates the capability of optimized quality and shortened exam time for neonatal tele-echocardiographic examinations in first test implementations.

### Conclusion

Remote control operation of the handheld ultrasound system appears to optimize the TeleEcho exam and facilitates supervision and interpretation of images with a simultaneous live videoconferencing link.

Use of Virtual User Interface is expected to decrease TeleEcho examination call time.

This technology represents the next step in pediatric telemedicine.

*The views expressed are those of the author(s) and do not reflect the official policy of the Department of the Army, the Department of Defense or the U.S. Government.*  
*The investigators have adhered to the policies for protection of human subjects as prescribed in 45 CFR 46.*

Research funding provided by:  
DAMD17-03-1-0109 & AAMTI FY09